Updated: Risk of retained intubating stylet fragments in neonates





SAFETY NOTICE: 004/25

Issue date:	11 March 2025
Content reviewed by:	Maternity and Neonatal Safety Program Team, Clinical Excellence Commission Maternity and Newborn Team, Health and Social Policy Branch, NSW Health HealthShare NSW LHD Neonatologists
Distributed to:	Chief Executives Directors of Clinical Governance Director, Regulation and Compliance Unit
KEY MESSAGE:	There continues to be a potential risk of shearing and retention of the intubating stylet sheath during neonatal intubation. Risk assessment and implementation of risk mitigation strategies is essential to minimise the risk of harm to neonates.
ACTION REQUIRED BY:	Chief Executives and Directors of Clinical Governance
REQUIRED ACTION:	 Distribute the Safety Notice to all relevant clinical staff. Include this Safety Notice in relevant handovers and safety huddles. Review and revise local risk assessments and associated strategies to mitigate the risk of stylet fragment retention. Liaise with the local Clinical Product Managers to ensure the size of the stylets are compatible with the endotracheal tubes in use. Report any incidents associated with these devices into ims+ and TGA.
DEADLINE:	July 2025
We recommend you also inform:	Directors, Managers and Staff of: • Maternity, Neonatal and Paediatric Services • Surgical / Anaesthetic Services • Emergency Departments • Retrieval Services and NSW Ambulance • Other clinicians who may be required to perform neonatal resuscitation
Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx http://internal.health.nsw.gov.au/quality/sabs/index.html
Review date:	March 2026

Contact: Clinical Excellence Commission 02 9269 5500

02 9209 5500

cec-recalls@health.nsw.gov.au

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What is updated in the Safety Notice from SN: 003/22?

This safety notice replaces *SN*: 003/22 Risk of retained intubating stylet fragments in neonates, which has now been rescinded. It reinforces and updates recommendations to minimise the risk of harm to neonates when using intubating stylets during neonatal intubation.

Situation

There continues to be a potential risk of shearing and retention of the intubating stylet sheath during neonatal intubation.

This is a rare but life-threatening complication that may lead to partial or complete airway obstruction, impaired ventilation and additional invasive procedures.

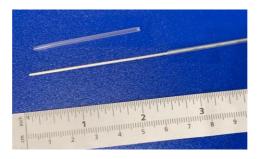


Figure 1 - Fragment of intubating stylet sheath

Background

Intubating stylets (also known as "introducers") are flexible, plastic coated (sheathed) wires used to assist with the correct positioning of an endotracheal tube (ETT). In some products, the plastic sheath is not bonded to the stylet wire. This plastic sheath is designed to minimise airway trauma if the stylet extends beyond the tip of the ETT and reduce friction during stylet insertion and withdrawal from the ETT.

Whilst no definitive cause of shearing of the stylet sheath is reported in the literature^{a-c}, it is suggested that repeated shaping of the stylet, reuse and friction between the ETT and the stylet during insertion and removal may be contributing factors. Friction may be highest if the stylet is a tight fit within the ETT.

Assessment

Due to the serious risk involved with retained fragments, it is important clinicians are aware of prevention strategies (see recommendations outlined below) and that they can recognise and manage retained intubating stylet fragments in the ETT or airway.

Recognition of retained stylet fragment(s) may include:

- Acute airway obstruction
- Airway injury
- Foreign body(s) on chest x-ray
- Partial or complete ETT occlusion
- Higher than expected airway ventilation pressures.

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Recommendations

- Do not use 6FG intubating stylets in 2.0 mm ETTs.
- Assess the need for the use of an intubating stylet.
- If used, follow the specific stylet's instructions for use and:
 - Check stylet size compatibility with the selected ETT size. Exercise additional caution with ETTs less than 3.0 mm, as these sizes may be outside the specifications for use of a stylet.
 - o Inspect the stylet sheath integrity before use.
 - Before intubation pause and ensure the stylet passes freely in and out of the ETT^d. If not
 do not use either the stylet or ETT. Retain the devices and escalate to the local clinical
 product manager for further advice.
 - o Avoid repeated sharp bending, maintain a smooth shape of the stylet.
 - o Inspect the stylet sheath integrity after use with a second clinician. Consider adding this step to local intubation checklists where available.
- Where possible do not re-use a stylet. Consider availability and preparation of additional stylets if there are multiple attempts to intubate.
- Always obtain a post intubation chest x-ray, with attention to the possibility of a retained sheath fragment.

If stylet sheath retention is suspected:

- Do not immediately extubate if the baby has stable ventilation.
- Seek immediate expert assistance including activation of a Clinical Emergency Response System (CERS) response as per local processes.
- Obtain an urgent chest x-ray. Request immediate review by a consultant or radiologist for possible sheath fragment retention. The fragment may be located within the ETT and/or below the ETT.
- Do not use a suction catheter or administer surfactant as this may push the fragment lower into the bronchial tree.
- Ensure local orientation and neonatal resuscitation training programs include information on the risks, prevention, recognition and management of retained intubating stylet fragments.

References:

- a) Chiou HL, Diaz R, Orlino E Jr, Poulain FR: Acute airway obstruction by a sheared endotracheal intubation stylet sheath in a premature infant. J Perinatol. 2007, 27:727-9.
- b) Gray MM, Umoren RA, Harris S, Strandjord TP, Sawyer T. Use and perceived safety of stylets for neonatal endotracheal intubation: a national survey. *J Perinatol*. 2018 Oct;38(10):1331-1336.
- c) Viswanathan S, Rodriguez Prado Y, Chua C, Calhoun DA. Extremely Preterm Neonate with a Tracheobronchial Foreign Body: A Case Report. Cureus. 2020 Apr 13;12(4): e7659.
- d) NSW Health, 2025, SA: 002/25, Managing the shortage of neonatal and paediatric endotracheal tubes. Accessed 7 March 2025. Available online at: https://internal.health.nsw.gov.au/quality/sabs/

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